

FW

David W. Osborne  
Registered Patent Attorney  
osborne@tnw.com

P. Scott Smith  
Registered Patent Attorney  
scottsmith@tnw.com

M. Wayne Western  
Garron M. Hobson  
Peter M. de Jonge  
Steve M. Perry  
Gary P. Oakeson  
David W. Osborne  
Jason R. Jones  
Christopher L. Johnson  
Robert R. Mallinckrodt  
Erik S. Ericksen, M.S.  
Alex W. Haymond  
Gordon K. Hill  
Todd B. Alder, Ph.D.  
Robert L. Lundstrom  
P. Scott Smith  
J. Abby Barraclough  
Ronald A. Burchett  
Sara Anderson Snow  
Jed H. Hansen, M.S.  
Richard L. Green, Ph.D.  
Bradley P. Cardon

Technical Consultants  
Randy M. Braegger  
David G. Wilding  
Shung H. Chan, M.S.

August 14, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/700,838 filed November 3, 2003  
First Named Inventor: David Fikstad  
Title: **PHARMACEUTICAL COMPOSITIONS WITH  
SYNCHRONIZED SOLUBILIZER RELEASE**  
Group Art Unit: 1614  
Attorney Docket No.: 01235-23625

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. § 1.56 and 1.97 is a Supplemental Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. § 1.97 and 1.98:

- ☒ Form **PTO/SB/08A** and **PTO/SB/08B** list of 4 references submitted for consideration.
- ☒ Legible copies of the listed non-patent documents, unpublished U.S. applications and foreign documents or their relevant portions are included.
- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.

www.tnw.com

8180 South 700 East  
Suite 350  
Sandy, Utah 84070-0562  
t. 801.566.6633  
f. 801.566.0750  
patlaw@tnw.com

U.S. Mailing Address:  
P.O. Box 1219  
Sandy, Utah 84091-1219

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- ☐ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application no. \_\_\_\_\_, filed on \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☒ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☐ Check No. \_\_\_\_\_, which includes the amount of \$180.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

Very truly yours,



David W. Osborne  
Attorney for Applicant  
Registration No. 44989

THORPE NORTH & WESTERN, LLP  
Customer No. 20,551  
P.O. Box 1219  
Sandy, Utah 84091-1219  
Telephone: (801) 566-6633

  
DO/PSS/rs



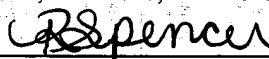
IN THE UNITED STATES PATENT & TRADEMARK OFFICE

ART UNIT: 1614  
EXAMINER: Ardin H. Marschel  
FIRST NAMED  
INVENTOR: David Fikstad  
SERIAL NO.: 10/700,838  
FILED: 11/3/2003  
CONFRM. NO.: 5766  
FOR: PHARMACEUTICAL  
COMPOSITIONS WITH  
SYNCHRONIZED SOLUBILIZER  
RELEASE  
DOCKET NO.: 01235-23625

**CERTIFICATE OF MAILING**  
**UNDER 37 C.F.R. § 1.8**

DATE OF DEPOSIT: August 19, 2008

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Rebecca Spencer

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form **PTO/SB/08A** and Form **PTO/SB/08B** which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c).

Applicant respectfully submits that this Information Disclosure statement is filed pursuant to:

☐ 37 C.F.R. § 1.97(b)(1), (3) or (4), within three months of the filing date of the application or request for RCE, or before a first office action on the merits, whichever occurs last;

☒ 37 C.F.R. § 1.97(c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in 37 C.F.R. § 1.17(p); or

☐ 37 C.F.R. § 1.97(d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in 37 C.F.R. § 1.17(p).

While no representation is made that any of these references may be “prior art” within the meaning of that term in accordance with 37 C.F.R. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☒ A legible copy of each of the listed non-patent literature, unpublished U.S. applications and foreign documents or their relevant portions is enclosed.

☐ Copies of the references listed in the accompanying Form PTO/SB/08A and PTO/SB/08B are NOT enclosed because, under 37 C.F.R. § 1.98.(d), they were previously cited

by or submitted to the Office in application number \_\_\_\_\_, which is relied upon for an earlier filing date under 37 C.F.R. § 1.20.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.


Dated August 19, 2008.

Very truly yours,



David W. Osborne  
Attorney for Applicant  
Registration No. 44989

THORPE NORTH & WESTERN, LLP  
Customer No. 20,551  
P.O. Box 1219  
Sandy, Utah 84091-1219  
(801) 566-6633

  
DO/PSS/rs  
Enclosures



DOCKET NO. 01235-23625

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FIRST NAMED

INVENTOR: David Fikstad

SERIAL NO.: 10/700,838

FILED: 11/3/2003

CONFIRM. NO.: 5766

FOR: PHARMACEUTICAL

COMPOSITIONS WITH  
SYNCHRONIZED SOLUBILIZER  
RELEASE

ART UNIT: 1614

EXAMINER: Ardin H. Marschel

CERTIFICATE OF DEPOSIT

UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, under 37 C.F.R. §1.8 on the date indicated below and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Rebecca Spencer*  
Rebecca Spencer

*Aug 19 2008*  
Date of Deposit

PROMPTNESS CERTIFICATE UNDER 37 C.F.R. §1.97(e)

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

\_\_\_ I hereby certify that each item contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

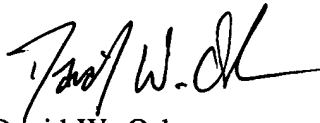
  x   I hereby certify that no item contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Please charge any additional fees or credit any overpayment to Deposit Account No. 20-0100.


DATED this 19<sup>th</sup> day of August, 2008.

Respectfully submitted,



David W. Osborne  
Attorney for Applicant  
Registration No. 44989

THORPE NORTH & WESTERN, LLP  
Customer No. 20,551  
P.O. Box 1219  
Sandy, Utah 84091-1219  
Telephone (801) 566-6633

  
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